JUN 1 9 2001

K010902

510(k) SUMMARY

Manufacturer and Submitter

Porex Surgical, Inc.
15 Dart Road
Newnan, GA 30265

Tel: (678) 479-1610
Fax: (770) 423-1437

Contact: Howard Mercer, Ph.D.
e-mail: howard_mercer@porex.com

Date: June 14, 2001

Trade Name: Medpor® Quad Motility Implant
Classification Name: 21CFR §886.3320 Eye Sphere Implant - Class II Device

Substantially equivalent to:
A) MEDPOR® Biomaterial Spherical Orbital Implants by Porex Surgical Inc.
B) MEDPOR® Biomaterial Conical Orbital Implant by Porex Surgical Inc.
C) LEE ALLEN'S UNIVERSAL MOTILITY IMPLANT

Device description:

A MEDPOR® Quad Motility Implant that is made of porous polyethylene and is essentially a sphere with anterior mounds to form a lock and key fit with a subsequently fitted prosthesis.

Comparison with predicate device

The device of this submission is identical to the predicate devices of Porex Surgical in all aspects except for the addition of the anterior mounds of the Lee Allen predicate device.

The posterior surface of the proposed implant remains essentially a hemisphere. The anterior surface is modified so there are four rounded protruding mounds. The device is implanted in the same manner as the predicate devices. However motility is achieved by duplicating the topography of the anterior implant surface in the casting made by the ocularist. The prosthesis that is produced from the casting will fit over and around the mounds, providing a lock and key fit and therefore yielding a prosthesis that will better follow the movement of the underlying implant.

Indications for Use:

The MEDPOR® Quad Motility Implant is indicated to fill the void left by the eviscerated or enucleated eye globe and where motility without direct coupling is desired.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Porex Surgical, Inc.
c/o Howard Mercer Ph.D.
Regulatory Affairs Manager
15 Dart Rd.
Newnan, GA 30265

Re: K010902
Trade Name: MEDPOR® Quad Motility Implant
Regulatory Class: II
Regulation: 886.3320
Product Code: 86 HPZ
Dated: March 23, 2001
Received: March 26, 2001

Dear Dr. Mercer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indication for Use

Applicant: Porex Surgical Inc.

510(k) Number: K010902

Device Name: Medpor® Quad Motility Implant

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K010902

Prescription Use: ✓ OR Over the Counter Use: _____
(Per 21CFR801.109